

Exhibit 1

Amphibole Content of Cosmetic and Pharmaceutical Talcs

by A. M. Blount*

Pharmaceutical and cosmetic-grade talcs were examined for asbestiform amphibole content using a new density-optical method. Talcs under the Food and Drug Administration are not regulated as to asbestos content; however, all talcs were well below the level mandated by the Occupational Safety and Health Administration for industrial talcs. Only one was found to contain an amphibole particle size distribution typical of asbestos.

Introduction

In 1973 the Food and Drug Administration (FDA) proposed a regulation on the permissible asbestos content of talc (1). This regulation proposed to limit the amount of amphibole minerals to less than 0.1% and chrysotile to less than 0.01%. However, the optical microscopy method proposed was so complicated, lengthy, and subject to error that the proposed method was never finalized. Since then no final ruling has been issued.

The Occupational Safety and Health Administration, on the other hand, has been more rigorous and has instituted regulations despite the lack of methods to carry out the required measurements. One regulation, instituted in 1986, defines amphibole minerals as asbestos if the length to width ratio is 3:1 or greater. Because many nonfibrous cleavage fragments of amphibole minerals have a 3:1 aspect or greater and because there is no good evidence for adverse effects of these particles, a stay has been in effect on this part of the regulation (2). The second applicable regulation is the Hazard Communication Regulation (3), which applies to all chemicals used in the workplace. Specifically, it requires labeling of substances containing > 1% of a chemical hazardous to health and > 0.1% of a carcinogenic chemical.

Unfortunately, asbestos and amphiboles cannot be measured using currently developed methods to the level of 0.1% in the presence of talc. Some investigators have suggested that tremolite can be measured to that level by X-ray diffraction. But others have shown that the peak intensities vary between nonfibrous and fibrous tremolite (4) so that the 0.1% level of detection and measurement is doubtful except in cases where the sample has been spiked so that the exact nature of the tremolite is known. For anthophyllite there is little argument about the fact that detection cannot be made to 0.1%. However, the main problem with using X-ray diffraction for detection of amphibole minerals is that it gives no information about the shape of the particles, and shape is important in view of the uncertainty in the outcome of the asbestos regulation pertaining to nonfibrous amphiboles.

The talcs that are pharmaceutical grade fall under the domain of the FDA and are therefore nonregulated in regard to fibrous mineral content. In the course of developing a technique to facilitate quantification of amphiboles in talc (5), pharmaceutical and high-grade talcs were examined. They were found to have very low amphibole content and, because of this, were extensively used in examining the lower limit of detection of the new method. The purpose of this paper is to describe the results of analyses for content and shape of amphibole mineral fragments in cosmetic and pharmaceutical talc powders of the United States.

Methods

The method proposed by the FDA in 1973 for analysis of talc was an optical procedure as described below (1):

Weigh out 1 milligram of a representative portion of talc on each of two microscope slides. Mix the talc with a needle on one slide with a drop of 1.574 refractive index liquid, and then the other with 1.590 liquid, and place on each a square or rectangular cover glass sufficiently large so that the liquid will not run out from the edge (ca. 18 mm square) and will provide a uniform particle distribution. Fibers counted by this method should meet the following criteria: (i) Length to width ratio of 3 or greater (ii) length of 5 μ m or greater (iii) width of 5 μ m or less. Count and record the number of asbestos fibers in each 1 milligram as determined from a scan of both slides with a polarizing microscope at a magnification of approximately 400 \times . In the 1.574 refractive index liquid, chrysotile fibers with indices less than 1.574 in both extinction positions may be present; in the 1.590 refractive index liquid, the other five amphibole types of asbestos fibers with indices exceeding 1.590 in both extinction positions may be present. Check the extinction and sign of elongation for tentative identification. For specific identification of asbestos fibers, make additional mounts in appropriate refractive index liquids, and refer to the optical crystallographic data in the table. A count of not more than 1000 amphibole types of asbestos and not more than 100 chrysotile asbestos fibers per milligram-slide constitutes the maximum limit for the presence of these asbestos fibers in talc. These limits assure a purity of at least 99.9 percent free of amphibole types of asbestos fibers and at least 99.99 percent free of chrysotile asbestos fibers.

The problem with the proposed method is that talc flakes are often oriented vertically or at a sufficient angle that they appear to be needles and thus must be tested for refractive index (Fig. 1). A typical number of such particles is five per field of view. This

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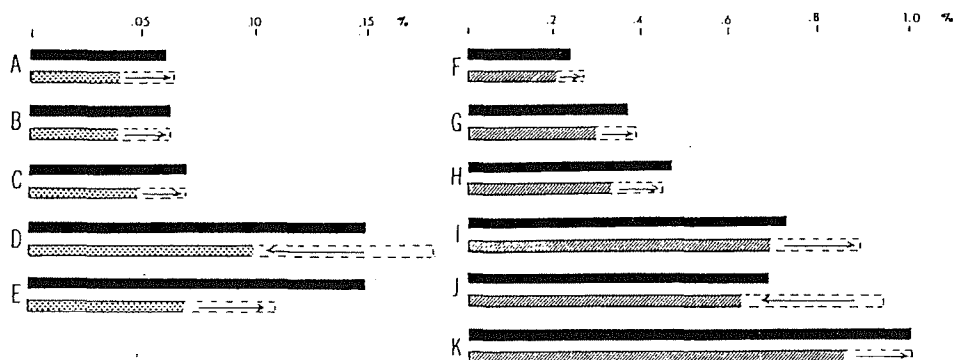


FIGURE 3. Percent tremolite in talc as determined by the centrifuge/optical method (shaded bars) compared with that actually present in experimental mixtures (black bars). The dashed part of the shaded bars indicates +2 SD (right arrow) or -2 SD (left arrow).

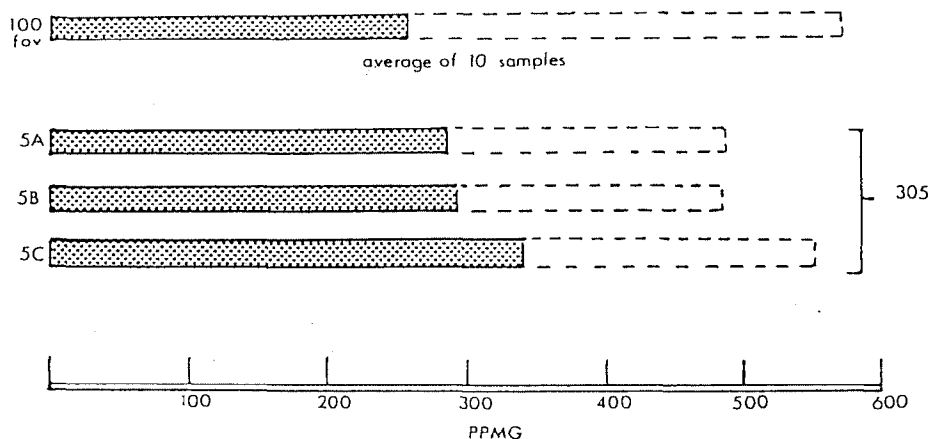


FIGURE 4. Comparison of traditional (100 FOV) count with centrifuge/optical count of same talc. The three lower bars indicate the values in particles/mg obtained by the centrifuge/optical method for three 60-mg samples. The top bar is the average of ten 100 FOV (traditional method). The dashed part of all the bars is +2 SD.

ways: for the traditional method by calculating in the usual way from multiple analyses and for the centrifuge method by means of the Poisson distribution from single counts. Standard deviations are high for the centrifuge method because of the very few particles counted. These could be decreased by making a larger count, but since the purpose of the study was to find a reasonably rapid method of monitoring amphibole content of talcs, larger counts were not generally made.

Results

High-grade talc products from five deposits in Montana, three in Vermont, and one each in North Carolina and Alabama were examined using the centrifuge/optical method. In addition, four talcs from outside the U.S. but available in the U.S. market were included in this study. Talcs from other districts in the U.S. were examined, but these talcs had grades with less stringent requirements and are not included in this report.

Results of particle counts are shown in Table 1. The FDA has equated 0.1% with 1000 particles per milligram. In order for amphibole particle content to be less than 0.1%, 20 or less particles must be observed in 20 FOV (5). Since all were well below this

value, more extensive counts were not generally made.

It should be borne in mind that the 0.1% indicated is percent by count and not percent by weight or volume. The question of the validity of this relation has been considered (5). Briefly, the relation implies (1000 amphibole particles)/(1,000,000 total particles). Counts of total particles per milligram of talc have shown that 1 million particles per milligram of talc is a low value. Most show at least 2 to 3 times this number. The only exception was a baby powder with very large flakes which showed 0.4 to 0.8 million particles per milligram. It was not clear, however, whether this was a true value or due to the problem of counting where large, flakey particles could potentially hide other particles even in the most carefully prepared samples. Using 1000 particles/mg = 0.1% would, in most samples, give a percentage value on the high side and in this sense be a conservative answer.

The counts shown in Table 1 were made of regulatory fibers i.e., aspect ratio > 3:1. In some samples there were as many or more nonregulatory particles of amphibole as regulatory fibers. The shape of the amphibole varies greatly and seems to be highly characteristic of each deposit. In Table 1, the particles having aspect ratios less than 6:1 are designated cleavages and prismatic pieces. Those greater than 6:1 and less than 15:1 are labeled

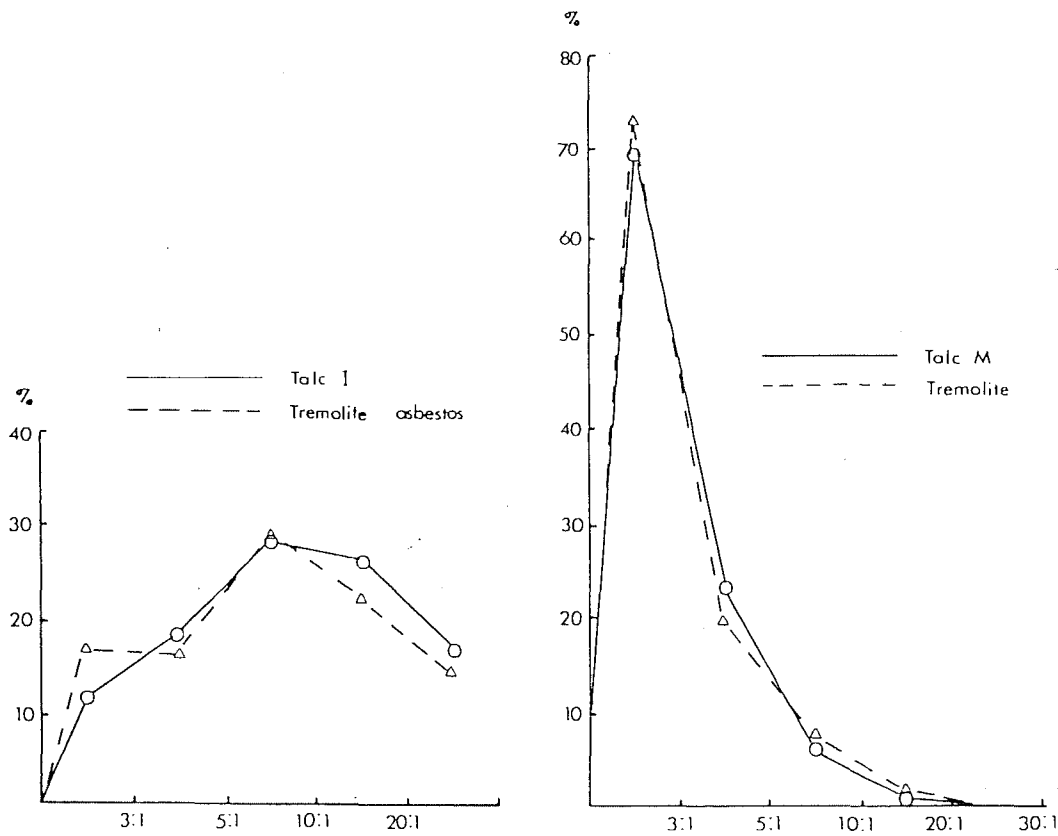


FIGURE 6. Percent amphiboles in each aspect ratio group for talc sample I (left) and M (right) compared with tremolite asbestos (7) and tremolite (nonasbestiform) (7).

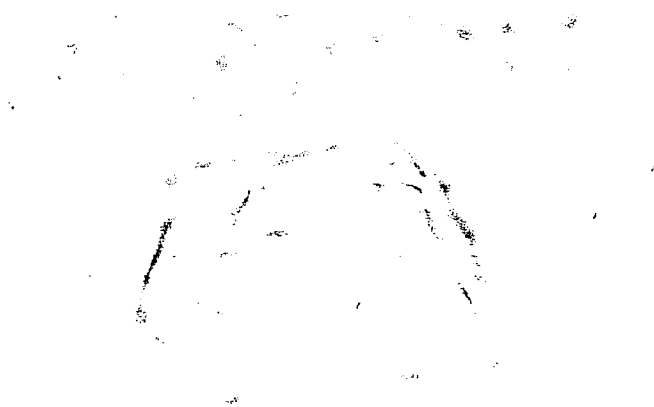


FIGURE 7. Particle of amphibole in centrifuged sample M. Width of view 0.07 mm and 1.584 refractive index liquid. Particle is on a membrane filter.

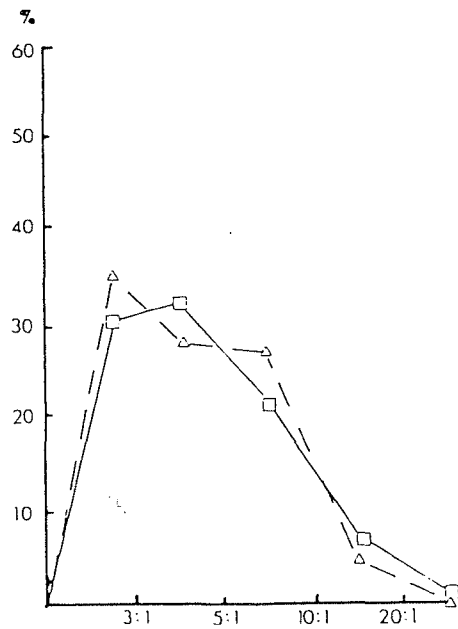


FIGURE 8. Percent amphiboles in each aspect group for a sample handled in two ways: solid line shows results using traditional method and dashed line shows results using centrifuge method. Dimensions of 100 particles measured for each curve.

THE NEWARK MUSEUM

C. J.P.G.

February 10, 1992

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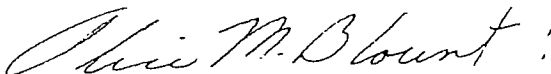
Dear Dr. Refregier:

Slim Thompson called recently about my paper in Environmental Health Perspectives. He said that you had been in contact with him. I am not trying to cause the talc industry any problems. I think lack of knowledge is a more serious problem. I have been told by the Industrial Hygienist that consults for this institution that all talc contains asbestos and we should not use any products containing talc.

The reason I have carried out this study is that I am asked to analyze very pure talcs for amphiboles. It takes a great deal of time to do 100 fields of view. Sometimes it is necessary to go to 1000 f.o.v. It is not fun! It seemed to me that there had to be an easier way, and to establish the validity of a method it is necessary to publish it for peer review. That is why the paper has appeared in print. Even if I use the old method, the new one is useful to give me an idea of how much effort will be needed to do the analysis to the accuracy required.

As I told Slim Thompson I have analyzed many talc samples (only a few reported) and often blind, in that I did not know their sources at the time the analyses were done. I do not believe I am misrepresenting these talcs. For individual deposits, the shape distribution and quantity remains fairly constant over time.

Sincerely yours,



Alice M. Blount

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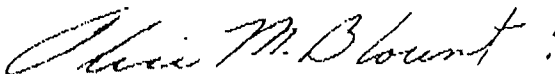
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Sincerely yours,



Alice M. Blount

A Italian

B Willow Creek, MT

C Pfizer, MT

D North Carolina

E Alabama

F Willow Creek, MT

G Barretts, MT (floated in Alabama)

H Italian

I Windsor, VT - baby powder

J Vermont

K Vermont

L Vermont

M Vermont

N Steetley, Ontario

O Montana Talc Co., MT

*floated - one from
Whitman & Tug*